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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,561	08/04/2006	Jin Sook Kim	B-6067PCT 623624-3	8314

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EXAMINER	
ML, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,561	KIM ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1 and 6-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/4/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 4/30/08 is acknowledged. Claims 1-13 are pending. Claims 1, and 6-13 are withdrawn due to non-elected invention groups or species. **Claims 2-5 are examined on the merits.** Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Diabetic complications cannot be prevented. There is no evidence that one would not ever get diabetic complications by consuming the claimed extract. Unless Applicant can show on the record that diabetic complication would be completely prevented in every instance, Applicant is requested to cancel the word "prevention".

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/5/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition contains a mixture of extracts from Euphorbiae radix, gingered Magnolia bark, parched Puerariae radix and Glycyrrhizae radix, does not reasonably provide enablement for preventing diabetic complications. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is well known in the art that the prevention of diabetic complication is a big challenge (Simpson et al., The prevention of type 2 diabetes-lifestyle change or pharmacotherapy? A challenge for the 21st century. Diabetes Research and Clinical Practice 59 (2003) 165-180). As indicated by Simpson et al that epidemiological studies have shown clearly that type 2 diabetes results from an interaction between a genetic predisposition and lifestyle factors including obesity, sedentary behavior and both calorie excess and various dietary constituents. It may not possible to maintain the lifestyle changes longer term (see Abstract). Simpson et al further states that the primary prevention, the ideal is to aim for elimination of the disease; this is currently not attainable (page 166, right column, 4th paragraph). As mentioned above, the invention only provides the description of composition contains a mixture of extracts from Euphorbiae radix, gingered Magnolia bark, parched Puerariae radix and Glycyrrhizae radix, and no description

regarding the prevention of diabetic complication is being disclosed in the specification. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to prevent diabetes, that Applicant is not enabled for method as instantly claimed. Considering this evidence, the skilled artisan, lacking information with regard to prevent diabetic complication, would necessarily need to perform tedious trial and error protocols without expectation of success in order to provide for the claimed invention.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Applicant argues that "The claimed invention is not the prevention of diabetes that the Examiner argues cannot be prevented. The claimed invention as recited above is for the prevention and treatment of the complications caused by diabetes. Accordingly, the Applicant submits that claims 2-5 are supported throughout the specification, *and, inter alia,* at page 21, lines 10-36 to page 29, lines 1-6 under the subtitle *"Test Example 2: Effect of inventive herbal extract mixture on treatment of diabetic complications"* wherein the treatment of five different diabetic induced complications is tested. Accordingly, the Applicant submits that the claimed subject matter is thoroughly described in the specification and claims 2- 5 are in compliance with 35 USC 112, first paragraph" (page 5, 4th paragraph).

This is not found persuasive. The specification does not reasonably provide enablement for preventing diabetic complications either. The Test Example 2 that Applicant refers to shows the herbal extract mixture on treatment of diabetic complications, but the prevention of diabetic complications. Therefore, unless Applicant can show on the record that diabetic complication would be completely prevented in every instance, Applicant is requested to cancel the word "prevention".

Claim Rejections -35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cho et al (US 2002/0146404 A1), Wang (CN 1273843), Zhang (CN 1151306), Yang (CN 1164401), and Sun (CN 1341441).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/5/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Cho et al disclose a crude drug composition for treating gastrointestinal dyskinetic diseases (see Title) comprising Magnoliae cortex and Glycyrrhiza Radix, which are washed, dried, mixed with proper ratio, pulverized (crushed) to obtain the pulverized form of crude drug composition [0066], the pulverized crude drug composition is mixed with 5-20-fold, volume of distilled water, alcohols such as methanol, ethanol, and the like, or the mixtures thereof, and is enfleuraged at the temperature ranging from 12-48 h, or extracted by sonication, reflux or conventional extraction to obtain an aqueous extract from of crude drug composition [0067]. Additionally, the herbal extract is filtered and concentrated at 40-80 °C under reduced pressure

[0068]. Cho et al further teach that Magnoliae cortex is a dried stem bark or dried root bark of *Magnolia officinalis* [0014]. Cho et al also teach that the pharmaceutical composition of the invention can be administered to a subject animal via various routs [0087], and provide a health food comprising a crude drug composition [0088].

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as a pharmaceutical, composition, or a functional food for the treatment of diabetic complications. It is deemed that the composition disclosed by Cho et al. is not precluded for carrying out the intended function of the claims.

Cho et al do not teach the corporation of Euphorbiae radix, and parched Puerariae radix into the composition. Cho et al do not teach the gingered Magnolia bark either.

Wang teaches a gastrointestinal health-care composition for treating weak spleen and stomach, diarrhea, stomach-ache and superficial or chronic gastritis comprising pueraria root (radix) etc, and the advantages of the composition include high health-care effect and no toxic by-effect (see Abstract).

Zhang teaches a composition for treating gastropathies etc comprising radix euphorbiae etc (see Abstract).

Yang teaches a composition for treating gastritis and duodenal ulcer prepared by processing Cortex *Magnoliae Officinalis* with ginger water (thus gingered Magnoliae bark) (see Abstract).

Sun teach a composition for treating gastrointestinal disease comprising Radix Glycyrrhizae etc made through parching Radix Glycyrrhizae etc (see Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for gastrointestinal care. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in gastrointestinal care.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for gastrointestinal care. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known

properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re* Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re* Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability to provide gastrointestinal care, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Cho et al, Wang, and Zhang since all of them teach compositions for gastrointestinal health care individually in the art. Since all the compositions yielded beneficial results in for gastrointestinal health care, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the

amount of the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the health condition of the patient.

As evidenced by Yang and Sun, it is a conventional practice to process herbal medicines through curing with ginger, or through the process of parching, thus it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the gingered Magnolia bark and parched Glycyrrhizae etc.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The Applicant notes that there are a plethora of patents disclosing compositions for treating gastrointestinal disease (253 issued US patents) and gastritis (22 issued US patents), and that the skilled person wanting to prepare a composition for treating diabetic complications is not likely to look to any of them, let alone the applications cited in the Office Action by the Examiner. On page 8 of the Office Action the Examiner states, *"In the instant case, all of the above-listed ingredients were known for gastrointestinal care. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for gastrointestinal health care."* (page 6, 2nd paragraph from the bottom).

This is not found persuasive. As indicated above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for gastrointestinal care. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re* Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

Applicant argues that "Examiner's statement is irrelevant to the novelty and obviousness of the claimed composition for the treatment of diabetic complications. One having ordinary skill in the art would not equate gastrointestinal disease and gastritis with diabetic complications. Furthermore, in view of all the possible art disclosing compositions for the treatment of gastrointestinal disease and gastritis, there is no motivation, either in the references or in the general knowledge in the art, for the skilled person to select the compounds of Cho et al, Wang, Zhang, Yang and Sun for preparing a compound comprising some of the disclosed ingredients for the treatment of diabetic complications" (page 7, 1st paragraph).

This is not found persuasive. As indicated above, the intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as a pharmaceutical, composition, or a functional food for the treatment of diabetic complications. It is deemed that the composition disclosed by the reference is not precluded for carrying out the intended function of the claims.

Applicant argues that "The new KSR Guidelines provide that *"When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness."* There is an utter dearth of such factual findings in the present Action, and in their stead only citation of irrelevant references for compounds for treating entirely different and unrelated ailments" (page 7, 2nd paragraph). Applicant further argues that "The Guidelines further admonish that *"Although a rejection need not be based on a teaching or suggestion to combine, a preferred search will be directed to finding references that provide such a teaching or suggestion if they exist. "'* There is no such motivation, either in the cited references or in the general knowledge in the art, as discussed above, and the Examiner has offered not one hint of where such motivation may be found" (Page 7, 3rd paragraph).

This is not found persuasive. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision Ex

parte Smith, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Applicant argues that "The Applicant thus requests that the Examiner provide explicit statements of fact on the record that explain precisely why it would have been obvious that the skilled person would select the four claimed ingredients from each of the five cited references and combine them in the claimed ranges to prepare a compound for the treatment of diabetic complications as recited in the pending claims" (page 7, last paragraph).

As stated above, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655